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Pesticide Registration Standard
2-Ethyl-1,3-Hexanediol

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This document contains information regarding reregistration of pesticide products containing 2-Ethyl-1,3-Hexandediol (6-12), including how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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Pesticide Registration Standard

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2-Ethyl-1,3-Hexanediol

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CHAPTER I: HOW TO REGISTER UNDER A REGISTRATION STANDARD

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1. Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or reregistering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

2. Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

> "(A) its composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of this Act;
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. However, the established approach to making these findings has been found to be defective on two counts.

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product by product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use the pesticide safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

3. Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

4. "Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 43 FR 29696, July 10, 1978; 43 FR 37336, August 22, 1978; and 45 FR 72948, November 3, 1980, as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the third chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

A. Data that are product specific, i.e. data that relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

B. Generic data that pertains to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products are also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concern the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert", ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed guidelines, 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed guidelines,43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

5. Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered are all data which are described by all of the following criteria:

A. The data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;

B. The data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for registration, or to support or maintain an existing registration;

C. They are the kind of data which are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);

D. The Agency has found the data to be valid and usable in reaching regulatory conclusions; and

E. They are not data for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for that data.

Each applicant for registration or reregistration of a manufacturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

6. Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in the third chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the "product specific" data gaps on a "product by product" basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether the data in question are "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

7. Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

CHAPTER II: REGULATORY POSITION AND RATIONALE

1. Introduction
2. Description of Chemical
3. Regulatory Position
4. Regulatory Rationale
5. Criteria for Registration under the Standard
6. Required Labeling
7. Tolerance Reassessment

1. Introduction

This chapter presents the Agency's regulatory position and rationale based on an evaluation of all registered products containing 2-ethyl-1,3-hexanediol as the sole active ingredient. After briefly describing the chemical, this chapter presents the regulatory position and rationale, the criteria by which applicants for registration of 2-ethyl-1,3-hexanediol products will be approved, labeling considerations, and tolerance reassessment. A summary of data requirements is contained in Chapter III. A discussion of the data upon which this regulatory position is based is presented in each of the disciplinary chapters, IV through IX.

2. Description of Chemical

2-ethyl-1,3-hexanediol, also known as "6-12", is registered as an insect repellent for use on human skin, clothing, and window and door screens, excluding use in commercial food preparation and serving areas. The Chemical Abstracts Service (CAS) Registry number for 2-ethyl-1,3-hexanediol is 94-96-2. The OPP Internal Control Number (EPA Shaughnessy number) is 041001.

3. Regulatory Position

2-ethyl-1,3-hexanediol as described in this Standard may be registered for sale, distribution, reformulation and use in the United States. The Agency has considered the scientific data obtained from the open literature as of January 14, 1981, and those data submitted by the registrants up through the time of publication of this Standard. Based upon the review of these limited data, the Agency finds that none of the risk criteria found in section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations was met or exceeded for 2-ethyl-1,3-hexanediol. The Agency has determined that 2-ethyl-1,3-hexanediol does not appear to cause an unreasonable adverse effect, when used in accordance with proper label directions and precautions. 2-ethyl-1,3-hexanediol products currently registered may be reregistered subject to the conditions imposed for data requirements. New products may be registered under this Standard and are subject to the same requirements.

4. Regulatory Rationale

Limited data are available to support the registration of 2-ethyl-1,3-hexanediol, with the exception of a primary dermal irritation study and efficacy data. All other acute and chronic toxicology studies and product chemistry studies are either not available or not usable by current standards. There are no environmental fate or ecological effects data.

Despite the lack of data, the Agency has concluded that it should continue the registration for this chemical for the following reasons:

A. No valid, adverse effects data of regulatory concern have been uncovered in the review of the studies which have been received. Therefore, the benefits demonstrated by the sale of this product outweigh the known risks, when label directions are followed.

B. Incidents of 2-ethyl-1,3-hexanediol ingestion, as well as eye and other means of exposure have been reported. However, no indication of any resulting problems has been given. (EPA 1980, MRID #GS00200019).

C. In accordance with FIFRA, the Agency's policy is not to cancel routinely the registration of products for which it lacks data or to withhold registration merely for the lack of data. (See Sections 3(c)(2)(B) and 3(c)(7) of FIFRA.) Rather, publication of the Standard provides a mechanism for identifying data needs, and registration under the Standard allows for upgrading of labels during the period in which the required data are being generated. When these data are received, they will be reviewed by the Agency, and the registrability of the chemical will be reassessed.

5. Criteria for Registration Under The Standard

To be subject to this Standard, products must meet the following conditions:

- contain 2-ethyl-1,3-hexanediol as the sole active ingredient,
- bear required labeling, and
- conform to the product composition standard, acute toxicity limits, and use pattern requirements as specified in part A.1., 2., and 3., and B.1., 2., and 3., respectively.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in this Standard, including a commitment to fill data gaps on a time schedule specified by the Agency and, when applicable, offering to pay compensation to the extent required by 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D). As discussed in Chapter I, applicants for registration under this Standard should contact the Agency for specific instructions, including updated information on data requirements and companies whose data must be cited and to whom compensation must be offered.

A. Manufacturing-Use Products

1) Product Composition Standard

To be covered under this Standard, manufacturing-use 2-ethyl-1,3-hexanediol products with any percentage of active ingredient are acceptable with an appropriate certification of limits.

2) Acute Toxicity Limits

Because of the intended use of manufacturing-use 2-ethyl-1,3-hexanediol products, there are no acute toxicity limits.

3) Use Patterns

To be covered under this Standard, manufacturing-use 2-ethyl-1,3-hexanediol must be labeled to allow for formulation only into end-use repellents, which are intended for application to human skin and/or window and door screens, excluding use in commercial food preparation and serving areas.

B. End-Use Products

1) Product Composition Standard

End-use products with any percentage active ingredient with the appropriate certification of limits will be considered under this Standard.

2) Acute Toxicity Limit

Because of the high level of exposure resulting from direct skin application, the Agency will consider the registration of any ready-to-use, impregnated material, or pressurized spray in the following categories:

	Toxicology Category			
	I	II	III	IV
Acute Oral Toxicity	No	No	Yes	Yes
Acute Dermal Toxicity	No	No	Yes	Yes
Acute Inhalation Toxicity	No	No	Yes	Yes
Primary Dermal Irritation	No	No	Yes	Yes

Additionally, end-use products must not be corrosive to the eye (cause irreversible destruction of ocular tissue) or cause corneal involvement or irritation persisting for 21 days or more.

3) Use Pattern

To be considered under this Standard, end-use products must bear directions for use as an insect repellent to be used in direct skin application and clothing application on humans and/or window and door screens, excluding use in commercial food preparation and serving areas.

6. Required Labeling

All manufacturing-use and end-use 2-ethyl-1,3-hexanediol products must bear appropriate labeling as specified in 40 CFR 162.10. The guidance package which accompanies this Standard contains specific information regarding label requirements.

A. Manufacturing-use Products

All manufacturing-use 2-ethyl-1,3-hexanediol products must list on the label the intended end-uses of formulated products produced from manufacturing-use products. All manufacturing-use product labels must bear the following statement:

"For Formulation into End-Use Insect Repellent Products Intended Only for Nonfood Uses."

B. End-use Products

2-ethyl-1,3-hexanediol has been shown to be a skin sensitizer. Unless data on individual products are submitted to the contrary, all end-use 2-ethyl-1,3-hexanediol products must bear the following statement:

"If skin irritation (rash or itching) develops, discontinue use."

Because this product is applied directly to the skin, including hands, the following statement must appear on all end-use labels:

"Wash hands before touching food."

For end-use products presenting claims for insects which might affect public health, the Agency will require registrants to submit or cite data to support these claims. The label on all products or substantially similar products, which claim that 2-ethyl-1,3-hexanediol repels the following pests, must be supported by company data or published literature:

black flies
chiggers
fleas
mosquitoes
sand flies (biting midges)
stable flies
ticks

7. Tolerance Reassessment

The current uses of this chemical are not subject to the requirement to obtain a tolerance under the provisions of the Federal Food, Drug, and Cosmetic Act Therefore, no tolerance reassessment is appropriate for this Standard.

CHAPTER III: SUMMARY OF DATA REQUIREMENTS AND DATA GAPS

1. Introduction
2. Manufacturing-Use Products
3. End-Use Products
4. Footnotes

1. Introduction

Applicants for registration of manufacturing-use and end-use 2-ethyl-1,3-hexanediol products must cite or submit the information identified as required in the tables in this chapter. The tables applicable to end-use products indicate whether the product to be tested is the technical grade or formulation. Data generated on one formulation may be used to satisfy the data requirement for a substantially similar formulation. Information on which product specific data requirements are already met is available in the guidance package.

Before each requirement is listed the section of the Proposed Guidelines which describes the type of data and when the data are required to be submitted [43 FR, 29696 of July 10, 1978; and 43 FR, 37336 of August 22, 1978]. Justification for why the test is required is provided in the Guidelines. A discussion of why data additional to those already submitted are necessary, or why data normally required are not necessary for this chemical, are explained in footnotes to the tables. The data requirements specified are the minimum that will be required. Areas where additional data may be required as the result of tiered testing are indicated.

2-Ethyl-1,3-Hexanediol
Product Specific Manufacturing-Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.61-3	Product Identity & Disclosure of Ingredients	yes	Each Product	no1/	1/	yes/1/
163.61-4	Description of Manufacturing Process	yes	Each Product	no	-	yes/1/
163.61-5	Discussion on Formation of Unintentional Ingredients	yes	Each Product	no	-	yes/1/
163.61-6	Declaration & Certification of Ingredients Limits	yes	Each Product	no	-	yes/April, 1982
163.61-7	Product Analytical Methods & Data	yes	Each Product	partially	1/	yes/April, 1982
163.61-8(c)(1)	Color	yes	Technical Grade of Active Ingredient	no	-	yes/1/
163.61-8(c)(2)	Odor	yes	Tech. Grade of A.I.	no	-	yes/1/
163.61-8(c)(3)	Melting Point	yes	Tech. Grade of A.I.	no	-	yes/1/

All footnotes are located at the end of Chapter III.
These data requirements are current as of March, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol

Product Specific Manufacturing-Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.61-8(c)(4)	Solubility	yes	Technical Grade of Active Ingredient	no	-	yes/1/
163.61-8(c)(5)	Stability	yes	Tech. Grade of A.I.	no	-	yes/1/
163.61-8(c)(6)	Octanol/Water Partition Coefficient	yes	Tech. Grade of A.I.	no	-	yes/1/
163.61-8(c)(7)	Physical State	yes	Tech. Grade of A.I.	no	-	yes/1/
163.61-8(c)(8)	Specific Gravity	yes	Tech. Grade of A.I.	no	-	yes/1/
163.61-8(c)(9)	Boiling Point	yes	Tech. Grade of A.I.	no	-	yes/1/
163.61-8(c)(10)	Vapor Pressure	yes	Tech. Grade of A.I.	no	-	yes/1/
163.61-8(c)(11)	pH	yes	Tech. Grade of A.I.	no	-	yes/1/

All footnotes are located at the end of Chapter III.
These data requirements are current as of March, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol

Product Specific Manufacturing-Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.61-8(c)(12)	Storage Stability	yes	Each Product	no	-	yes/1/
163.61-8(c)(13)	Flammability	yes	Each Product	no	-	yes/1/
163.61-8(c)(14)	Oxidizing/Reducing Action	yes	Each Product	no	-	yes/1/
163.61-8(c)(15)	Explosiveness	yes	Each Product	no	-	yes/1/
163.61-8(c)(16)	Miscibility	yes	Each Product	no	-	yes/1/
163.61-8(c)(17)	Viscosity Coefficient	yes	Each Product	no	-	yes/1/
163.61-8(c)(18)	Corrosiveness	yes	Each Product	no	-	yes/1/

All footnotes are located at the end of Chapter III.
These data requirements are current as of March, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol

Generic Manufacturing-Use Products Data Requirements: Environmental Fate (See Chapter V)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.62-7(b)	Hydrolysis	no 2/				
163.62-7(c)	Photodegradation	no				
163.62-8(b)	Aerobic Soil Metabolism	no				
163.62-8(c)	Anaerobic Soil Metabolism	no				
163.62-8(d)	Anaerobic Aquatic Metabolism	no				
163.62-8(e)	Aerobic Aquatic Metabolism	no				
163.62-8(f)	Microbial Metabolism:					
	(2) Effects of Microbes on Pesticides	no				
	(3) Effects of Pesticides on Microbes	no				

All footnotes are located at the end of Chapter III.
These data requirements are current as of March, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol
Generic Manufacturing-Use Products Data Requirements: Environmental Fate (See Chapter V)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.62-8(g)	Activated Sludge Metabolism	no3/				
163.62-9(b)	Leaching	no				
163.62-9(c)	Volatility	no				
163.62-9(d)	Adsorption/Desorption	no				
163.62-9(e)	Water Dispersal	no				
163.62-10(b)	Terrestrial Field Dissipation:					
	(1) Field & Vegatable Crops	no				
	(2) Tree Fruit & Nut Crop Uses	no				
	(3) Pasture Land Uses	no				
	(4) Domestic Outdoor Parks, Ornamental & Turf Uses	no				

All footnotes are located at the end of Chapter III.
These data requirements are current as of March, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol
Generic Manufacturing-Use Products Data Requirements: Environmental Fate (See Chapter V)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
	(5) Rights of Way, Shelterbelts & Related Uses	no				
163.62-10(c)	Aquatic Field Dissipation:					
	(1) Aquatic Food Crop Uses	no				
	(2) Aquatic Noncrop Uses	no				
	(3) Specialized Aquatic Uses	no				
163.62-10(d)	Terrestrial/Aquatic (Forest) Field Dissipation	no				
163.62-10(e)	Aquatic Impact Uses:					
	(1) Direct Discharge	no				
	(2) Indirect Discharge	no				
	(3) Wastewater Treatment	no				

All footnotes are located at the end of Chapter III.
These data requirements are current as of March, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol
Generic Manufacturing-Use Products Data Requirements: Environmental Fate (See Chapter V)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.62-10(f)	Combination & Tank Mix Field Dissipation	no				
163.62-10(g)	Long Term Field Dissipation Study	no				
163.62-11(b)	Accumulation in Rotational Crops	no				
163.62-11(c)	Accumulation in Irrigated Crops	no				
163.62-11(d)	Fish Accumulation	no				
163.62-11(e)	Special Studies Accumulation in Aquatic Noncrop Uses	no				
163.62-13	Disposal & Storage	no				

All footnotes are located at the end of Chapter III.
These data requirements are current as of March, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol
Product Specific Manufacturing-Use Products Data Requirements: Toxicology (See Chapter VI)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.81-1	Acute Oral Toxicity	yes	Each Product or Substantially Similar Product	no	-	yes/April, 1982
163.81-2	Acute Dermal Toxicity	yes	Ea. Prod. or Substan. Sim. Prod.	no	-	yes/April, 1982
163.81-3	Acute Inhalation Toxicity	yes	Ea. Prod. or Substan. Sim. Prod.	no	-	yes/April, 1982
163.81-4	Primary Eye Irritation	yes	Ea. Prod. or Substan. Sim. Prod.	no	-	yes/April, 1982
163.81-5	Primary Dermal Irritation	yes	Ea. Prod. or Substan. Sim. Prod.	yes	000004881	no
163.81-6	Dermal Sensitization	yes	Ea. Prod. or Substan. Sim. Prod.	yes	000004881	no
163.81-7	Acute Delayed Neurotoxicity	no 4/				
163.82-1	Suchronic Oral Toxicity	no 5/				
163.82-2	Subchronic 21-Day Dermal Toxicity	no 6/				

All footnotes are located at the end of Chapter III.
These data requirements are current as of March, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol
Generic Manufacturing-Use Products Data Requirements: Toxicology (See Chapter VI)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.82-3	Subchronic 90-Day Dermal Toxicity	yes	Technical Grade of Active Ingredient	no	-	yes/May, 1982
163.82-4	Subchronic Inhalation Toxicity	7/	Tech. Grade of A.I.			conditional
163.82-5	Subchronic Neurotoxicity	no 8/				
163.83-1	Chronic Dermal Toxicity	yes9/	Tech. Grade of A.I.	no	-	yes/Nov, 1985
163.83-2	Dermal Oncogenicity	yes	Tech. Grade of A.I.	no	-	yes/Nov, 1985
163.83-3	Dermal Teratogenicity	yes	Tech. Grade of A.I.	no	-	yes/May, 1982
163.83-4	Dermal Reproduction	yes	Tech. Grade of A.I.	no	-	yes/Nov, 1984
163.84-2 through -4	Mutagenicity	yes	Tech. Grade of A.I.	no	-	yes/May, 1982
163.85-1	Metabolism (Identification of Metabolites)	yes	Tech. Grade of A.I.	no	-	yes/Nov, 1982

All footnotes are located at the end of Chapter III.
These data requirements are current as of September, 1980. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol
Generic Manufacturing-Use Products Data Requirements: Residue Chemistry (See Chapter VII)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
-	Metabolism in Plants	no				
-	Metabolism in Animals	no				
-	Analytical Methods	no				
-	Residue Data: Crops-	no				
-	Residue Data: Processed Crops-	no				
-	Residue Data: Milk & Meat	no				
-	Storage Stability	no				

All footnotes are located at the end of Chapter III.
These data requirements are current as of March, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol
Generic Manufacturing-Use Products Data Requirements: Ecological Effects (See Chapter VIII)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.71-1	Avian Single-Dose Oral LD_{50}	no[10]				
163.71-2	Avian Dietary LC_{50}	no[10]				
163.71-3	Mammalian Acute Toxicity	no				
163.71-4	Avian Reproduction	no				
163.71-5	Simulated and Actual Field Testing for Mammals & Birds	no				
163.72-1	Fish Acute LC_{50}	no[10]				
163.72-2	Acute Toxicity to Aquatic Invertebrates	no[10]				
163.72-3	Acute Toxicity to Estuarine & Marine Organisms	no				
163.72-4	Embryolarvae & Life-cycle Studies of Fish & Aquatic Invertibrates	no				
163.72-5	Aquatic Organism Toxicity & Residue Studies	no				
163.72-6	Simulated or Actual Field Testing for Aquatic Organisms	no				

All footnotes are located at the end of Chapter III.
These data requirements are current as of March, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol

Product Specific End-Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.61-3	Product Identity & Disclosure of Ingredients	yes	Each Product	no	-	yes/1/
163.61-4	Description of Manufacturing Process	yes	Each Product	no	-	yes/1/
163.61-5	Discussion on Formation of Unintentional Ingredients	yes	Each Product	no	-	yes/1/
163.61-6	Declaration & Certification of Ingredients Limits	yes	Each Product	no	-	yes/1/
163.61-7	Product Analytical Methods & Data	yes	Each Product	partially	1/	yes/1/

All footnotes are located at the end of Chapter III.
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A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol
Product Specific End-Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.61-8(c)(1)	Color	yes	Each Product	no	-	yes/1/
163.61-8(c)(2)	Odor	yes	Each Product	no	-	yes/1/
163.61-8(c)(3)	Melting Point	no				
163.61-8(c)(4)	Solubility	no				
163.61-8(c)(5)	Stability	no				
163.61-8(c)(6)	Octanol/Water Partition Coefficient	no				
163.61-8(c)(7)	Physical State	yes	Each Product	no	-	yes/1/
163.61-8(c)(8)	Specific Gravity	yes	Each Product	no	-	yes/1/
163.61-8(c)(9)	Boiling Point	no				
163.61-8(c)(10)	Vapor Pressure	no				
163.61-8(c)(11)	pH	yes	Each Product	no	-	yes/1/

All footnotes are located at the end of Chapter III.
These data requirements are current as of March, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol
Product Specific End-Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.61-8(c)(12)	Storage Stability	yes	Each Product	no	–	yes/1/
163.61-8(c)(13)	Flammability	yes	Each Product	no	–	yes/1/
163.61-8(c)(14)	Oxidizing/Reducing Action	yes	Each Product	no	–	yes/1/
163.61-8(c)(15)	Explosiveness	yes	Each Product	no	–	yes/1/
163.61-8(c)(16)	Miscibility	yes	Each Product	no	–	yes/1/
163.61-8(c)(17)	Viscosity Coefficient	yes	Each Product	no	–	yes/1/
163.61-8(c)(18)	Corrosiveness	yes	Each Product	no	–	yes/1/

All footnotes are located at the end of Chapter III.
These data requirements are current as of March, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol
Product Specific End-Use Products Data Requirements: Toxicology (See Chapter VI)

Guidelines Citation	Name Of Test	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.81-1	Acute Oral Toxicity	yes	Each Formulation or Substantially Similar Formulations	See Guidance Package for Requirements for Each Formulation or Substantially Similar Formulation		
163.81-2	Acute Dermal Toxicity	yes	Each Formulation or Substantially Similar Formulations	See Guidance Package for Requirements for Each Formulation or Substantially Similar Formulations		
163.81-3	Acute Inhalation Toxicity	yes	Each Formulation or Substantially Similar Formulations	See Guidance Package for Requirements for Each Formulation or Substantially Similar Formulations		
163.81-4	Primary Eye Irritation	yes	Each Formulation or Substantially Similar Formulations	See Guidance Package for Requirements for Each Formulation or Substantially Similar Formulations		
163.81-5	Primary Dermal Irritation	yes	Each Formulation or Substantially Similar Formulations	See Guidance Package for Requirements for Each Formulation or Substantially Similar Formulations		
163.81-6	Dermal Sensitization	yes	Each Formulation or Substantially Similar Formulations	See Guidance Package for Requirements for Each Formulations or Substantially Similar Formulations		

All footnotes are located at the end of Chapter III.
These data requirements are current as of March, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

2-Ethyl-1,3-Hexanediol
Product Specific End-Use Products Data Requirements: Efficacy (See Chapter IX)

Site	Pest	Are Data Required?	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Reference	Must Additional Data be Submitted Under FIFRA 3(c)(2 (B)? If So, due when?
Humans: Direct Skin Application & Clothing	Black Flies	yes	Minimum of 20% Active Ingredient	yes	000001106, 000001109 000001112, 000001118 005000009, 005000164 005003264, 005003640 005006137	no
	Chiggers	yes	11/	partially	000001112, 005000130 005000299, 005002397	yes/April, 1983
	Fleas	yes	11/	partially	000001112, 000001181	yes/April, 1983
	Mosquitoes	yes	Min. of 20% A.I.	yes	12/	no
	Sand Flies (Biting Midges)	yes	11/	partially	000001106, 000001107 000001109, 000001112 005000164, 005003263 005000236, 005002669	yes/April, 1983
	Stable Flies	yes	Min. of 20% A.I.	yes	13/	no
	Ticks	yes	11/	partially	005002666	yes/April, 1983

All footnotes are located at the end of Chapter III.
These data requirements are current as of March, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

4. Footnotes

[1] These requirements must be fulfilled by each applicant. Data from other applications may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. These requirements must be filled at the time of registration or reregistration.

[2] Hydrolysis data are not required, since the structure of this compound indicates its reaction with water will not be a significant route of degradation.

[3] The requirement for the submission of the above data is currently being reserved. Consequently, the absence of acceptable data within this topic does not constitute a data gap.

[4] Acute delayed neurotoxicity data are not required, because this chemical is not expected to cause esterase depression, nor is it related to a substance which induces delayed neurotoxicity.

[5] Subchronic oral toxicity data are not required, because the use of this chemical does not need a tolerance or an exemption from a tolerance, does not need the issuance of a food additive regulation, and is not likely to result in repeated human exposure through an oral route.

[6] Subchronic 21-day dermal toxicity data are not required, because the direct application of this chemical to the skin requires a subchronic 90-day dermal toxicity test.

[7] Acute inhalation data are not available. It is, thus, not possible to determine if a subchronic inhalation test is needed. A test may be required, depending on the results of the acute inhalation test.

[8] Subchronic neurotoxicity data are not required, because this chemical is not expected to cause esterase depression, nor is it related to a substance which induces delayed neurotoxicity.

[9] This study is listed in the Guidelines as a Chronic Feeding Study and not as a Chronic Dermal Study. We believe this reference will provide useful guidance with respect to factors other than route of exposure, such as number of animals per dosage group, number of dosage groups, etc.

[10] Ecological effects data are not required, because of the limited annual production and the use pattern of this chemical.

[11] Sufficient efficacy data are not available to establish a minimum percentage of active ingredient for these pests. Testing will be required for existing products until a minimum level is established.

[12] The bibliographic citations, which partially or totally support the claim for mosquito repellency are as follows:

MRID#
GS0020005
GS0020007
GS0020011
000001106
000001107
000001109
000001112
000001114
000001115
000001116
000001117
000001118
000001121
000001123
000001166

MRID#
000001172
000004865
000004866
000004867
000004868
000004873
000004874
000004887
000004890
000004892
000004893
000004896
005000042
005000113
005000121

MRID#
005000126
005000128
005000130
005000141
005000164
005000165
005000167
005000169
005000170
005000172
005000187
005000222
005000231
005000236
005000280

MRID#
005000284
005000299
005002395
005002493
005002667
005002848
005003262
005003263
005003265
005003266
005004864
005006012
005006137
005006463
005006505

MRID#
005011438

[13] The bibliographic citations, which partially or totally support the claim for stable fly repellency are as follows:

MRID#
GS0020005
GS0020011
000001106
000001107
000001109
000001112

MRID#
000001114
000001115
000001116
000001117
000001118
000001121

MRID#
000001123
000004865
000004866
000004867
000004868
000004874

MRID#
000004892
000004893
000021737
005000164
005000236
005000268

MRID#
005002395

IV. PRODUCT CHEMISTRY

The available product chemistry data cannot be considered as acceptable to fill the data requirements for 2-ethyl-1,3-hexanediol. The studies are old, and the applicability of the data to the products currently manufactured has not been established. Registrants may use existing data by resubmitting it along with confirmation of its current applicability.

The Agency reminds registrants that chlorofluorocarbons (Freons) have been banned for use in pressurized products due to their having been demonstrated to cause a depletion in the ozone layer (43 FR 11318). Products containing Freon are not registrable under this Standard.

V. ENVIRONMENTAL FATE

1. Use Profile
2. Environmental Fate Profile
3. Exposure Profile

1. Use Profile

2-ethyl-1,3-hexanediol is an insect, mite, and tick repellent registered for direct application to human skin and human clothing for the repellency of a variety of insects. Those which fall into the area of public health concern, according to the Agency definition (44 FR 27932; May 11, 1979), include black flies, chiggers, fleas, mosquitoes, stable flies, sand flies, and ticks. Ready-to-use, pressurized liquids, and impregnated materials registered for skin application are labeled to warn against contact with eyes or lips; pressurized liquids are not to be sprayed directly into the face.

Window and door screens, excluding use in commercial food preparation and serving areas, may also be treated with 2-ethyl-1,3-hexanediol.

2. Environmental Fate

The minimum environmental fate data as required by the Agency under the Guidelines proposed in 43 FR 29712; July 10, 1978, are not required for 2-ethyl-1,3-hexanediol. These include hydrolysis and activated sludge data. Hydrolysis data are not necessary, because the structure of this compound indicates its reaction with water will not be a significant route of degradation, and the requirement for the submission of activated sludge data is currently being reserved. In addition if indirect or accidental discharge into an aquatic environment or a wastewater treatment system were to occur, the Agency has determined that the amount of such a discharge would not be of significant quantity to cause extensive environmental harm. Also, the potential use pattern as a repellent for humans and window and door screens is not expected to result in the introduction of significant amounts of this chemical into the environment.

3. Exposure Profile

No specific exposure data on 2-ethyl-1,3-hexanediol have been developed. Human exposure is clearly very high due to the direct application to the skin. The Agency has decided not to seek data to quantify exposure until the results of the additional required toxicology testing are reviewed. At that time the Agency will either:

1. Attempt to establish safety margins based on exposure as indicated by existing use directions, or
2. Use data developed for other similar chemicals, or
3. Seek additional exposure data from registrants of 2-ethyl-1,3-hexanediol.

VI. TOXICOLOGY

1. Introduction
2. Manufacturing-Use Products
3. End-Use Products
4. Summary of Major Data Gaps

1. Introduction

Little acceptable data exist for 2-ethyl-1,3-hexanediol, with the exception of a primary dermal irritation study. However, a low order of acute toxicity is suggested by studies done on mixtures.

2. Manufacturing-Use Products

Toxicology Profile

A human study (Kline and Gabriel 1965, MRID#000004881) indicates that 2-ethyl-1,3-hexanediol may be a weak primary skin irritant and/or weak skin sensitizer. Four out of 200 people showed a reaction. This study is acceptable to fulfill the data requirement for primary dermal irritation and skin sensitization, although it was not conducted in accordance with the requirements of the Guidelines.

Insufficient data were available to assess the chronic effects. One inadequate chronic dermal study suggests, that 2-ethyl-1,3-hexanediol might be oncogenic in female mice (Stenbaeck and Shubik 1974, MRID#005004319). The results of this study were not definitive, because of the discrepancies between the number of animals in the test groups and the number of total tumors. A linear trend analysis and a site-specific chi-square test was conducted with the information available in the study, which suggest a possible oncogenic potential. A firm conclusion cannot be made. This study does, however, further substantiate the need for additional chronic testing.

3. End-Use Products

Toxicology Profile

Limited acceptable data exists for the end-use products. The primary dermal irritation study performed with the manufacturing-use product will be acceptable to fulfill the skin sensitization data requirement for the end-use products. Registrants will be required to place a precautionary statement concerning skin sensitization on the label. Those registrants who do not wish to do this may submit data using the appropriate test animals, and following Guideline requirements, submit data which demonstrate that their product is not a skin sensitizer.

4. Summary of Major Data Gaps

Except for the primary dermal irritation study for the manufacturing-use products and the skin sensitization study for the manufacturing-use and end-use products, the full series of toxicological tests are required.

VII. RESIDUE CHEMISTRY

An allowable residue level (tolerance) for specific chemicals is determined by the Agency for the commodities on which they may occur. Since no 2-ethyl-1,3-hexanediol product is registered for use on food or feed crops, its use should not result in such residues. Therefore, there are no residue chemistry data requirements for this chemical.

VIII. ECOLOGICAL EFFECTS

There are no ecological effects data requirements for 2-ethyl-1,3-hexanediol. The Agency has determined, that if an accidental discharge of 2-ethyl-1,3-hexanediol into an aquatic environment or a wastewater treatment system were to occur, the amount of such a discharge would not be likely to be of significant quantity to cause extensive environmental harm. In addition the potential use pattern as a repellent for humans and window and door screens is not expected to result in the introduction of significant amounts of 2-ethyl-1,3-hexanediol into the environment.

IX. EFFICACY

1. Efficacy Profile
2. Factors Influencing Efficacy
3. Use Sites
4. Target Pests
5. Summary of Major Data Gaps

1. Efficacy Profile

The review of 2-ethyl-1,3-hexanediol data are limited to efficacy data only as they relate to public health applications. The Agency has provided for the waiver of efficacy data submission as a part of the registration process in all other instances (44 FR 27932; May 11, 1979).

2. Factors Influencing Efficacy

Available data indicate that several factors may influence the efficacy of repellents such as 2-ethyl-1,3-hexanediol. Elements such as minimum effective dose, rate of loss, desirability of the host, and avidity of the insect species directly contribute to the overall protection time of repellents (Smith et al. 1963, MRID #005000300). Indications also exist which support the theory that washoff by rainfall and perspiration appear to reduce effectiveness (Granett and Haynes 1945, MRID #000001112). Decreases in the relative humidity and absorption also appear to reduce effectiveness (Wood 1968, MRID #005011438 and Smith 1970, MRID #000001166).

3. Use Sites

In relation to certain public health pests, the majority of the test data reviewed by the Agency clearly indicate that 2-ethyl-1,3-hexanediol applied directly to human skin is an appropriate use method. Application to human clothing is also an appropriate method. Formulations to repel black flies, mosquitoes, and stable flies for either application method must contain at least 20% active ingredient. A minimum percentage of active ingredient has not yet been established for the other public health pests.

Insufficient information is available to support use against public health pests for window and door screens.

4. Target Pests

In general 2-ethyl-1,3-hexanediol when used as a repellent, may be adequate to superior, depending on the species of biting insect, the type of formulation and percentage of active ingredient. Effective control has been demonstrated for the following insects:

black flies
mosquitoes
stable flies

(Please refer to the table for efficacy in Chapter III for references.) A minimum of 20% active ingredient is required for all formulations with regard to these pests.

The following pests were not supported with sufficient data to demonstrate efficacy:

chiggers
fleas
sand flies (biting midges)
ticks

5. Summary of Major Data Gaps

The major data gaps for efficacy of this chemical are for the treatment of chiggers, fleas, sand flies (biting midges), and ticks in direct skin or clothing application to humans.

X. CASE BIBLIOGRAPHY

Guide to Use of This Bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. The bibliography is divided into two sections: (1) citations in numerical order that contributed information useful to the review of the chemical and are considered to be part of the data base supporting registrations under the standard, (2) an alphabetical listing of all documents identified in the literature search, and (3) a standard reference bibliography. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, a nine-digit numeric identifier. This number is unique to the citations and should be used at any time specific reference is required. This number is called the "Master Record Identifier" or "MRID". It is not related to the six-digit "Accession Number", which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. This is the third element in the citation. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to us in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submissions:

   (1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

   (2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

   (3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th,123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD NUMERICAL BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Standard

CASE GS0002 2-ethyl-1,3-hexanediol

MRID	CITATION
GS0020005	Haynes, H.L. (1971) Letter sent to J. Touhey dated Mar 10, 1970. [Concerns the registration of "6-12 PLUS". Efficacy data are attached for mixture with ethyl hexanediol, as well as ethyl hexanediol alone.] (Unpublished study received Jul 10, 1971 under 5769-57; submitted by ?; CDL:007435)
GS0020007	Lahr, P.H. (?) Tarrytown Technical Memorandum TTM-81:Synergistic Mixtures of 2-Ethyl-1,3-hexanediol and M-Diethyltoluamide. Exhibit D. (Unpublished study which includes Tables I and V received Apr 25, 1968 under 5769-27; prepared by Rutgers University, Entomology Department, submitted by ?; CDL:022577)
GS0020011	Lomax, J.L. (1970) Summary and Discussion of Repellent Test Results (Duration Type in the Lab.) (Unpublished study which includes Table I received Apr 25, 1968 under 5769-27; prepared by Rutgers University, Entomology Department, Submitted by ?; CDL:022577)
GS0020019	U.S. Environmental Protection Agency, Hazard Evaluation Division (1980) Summary of Reported Pesticide Incidents Involving Ethyl Hexanediol. Pesticide Monitoring System Report No. 374.
GS0020024	Bontoyan, W., ed. (1976) Manual of Chemical Methods for Pesticides and Devices. U.S. Environmental Protection Agency, Office of Pesticide Programs, Technical Services Division, Chemical and Biological Investigations Branch. (Available from Association of Analytical Chemists, Arlington, VA)
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OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD ALPHABETICAL BIBLIOGRAPHY
Listing of All Documents Identified in the Literature Search

CASE GS0002 2-ethyl-1,3-hexanediol

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000001111 Union Carbide Corporation (1970) Summary of 1969 Test Results with Personal Insect Repellent Formulations Containing (1) 25% 2-Ethyl-1,3-Hexanediol and 5% N,N-Diethyl-Meta-Toluamide, (2) 30% 2-Ethyl-1,3-Hexanediol and (3) 15% N,N-Diethyl-Meta-Toluamide: [Insect Repellent Spray: Exhibit A]. (Unpublished study received Feb 26, 1970 under 3282-46; CDL:007760-A)

000001123 Union Carbide Corporation (1970) Summary of 1969 Test Results with Personal Insect Repellent Formulations Containing (1) 40.0% 2-Ethyl-1,3-Hexanediol and 10.0% N,N-Diethyl-Meta-Toluamide (2) 40% 2-Ethyl-1,3-Hexanediol: Exhibit A. (Unpublished study that includes appended letter, received Apr 9, 1970 under 5769-51; CDL:007764-A)

000001114 Union Carbide Corporation (1970) Summary of 1969 Test Results with Personal Insect Repellent Formulations Containing (1) 40.0% 2-Ethyl-1,3-Hexanediol and 8.0% N,N-Diethyl-Meta-Toluamide (2) 48.6% 2-Ethyl-1,3-Hexanediol: [Insect Repellent Towelette]: Exhibit A. (Unpublished study received May 14, 1970 under 5769-44; CDL:007761-A)

000001106 Union Carbide Corporation (1970) Summary of 1969 Test Results with Personal Insect Repellent Formulations Containing (1) 56.0% 2-Ethyl-1,3-Hexanediol and 9.1% N,N-Diethyl-Meta-Toluamide and (2) 65% 2-Ethyl-1,3-Hexanediol: Exhibit A. (Unpublished study received Apr 9, 1970 under 3282-44; CDL:007757-A)

000001107 Union Carbide Corporation (1970) Summary of 1969 Test Results with Personal Insect Repellent Formulations Containing (1) 80% 2-Ethyl-1,3-Hexanediol and 10% N,N-Diethyl-Meta-Toluamide (2) 80% 2-Ethyl-1,3-Hexanediol and (3) 50% N,N-Diethyl-Meta-Toluamide: Exhibit A. (Unpublished study received Mar 24, 1970 under 5769-27; CDL:007758-A)

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